



10/521,841

601-I-134PCTUS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Wieder
SERIAL NO. : 10/521,841 EXAMINER: Meera Natarajan, PhD
FILED: July 27, 2005 ART UNIT: 1643
FOR : ALPHA 5 BETA 1 AND ITS ABILITY TO REGULATE THE CELL
SURVIVAL PATHWAY

DECLARATION OF ROBERT WIEDER

I, Robert Wieder, hereby declare that:

1. I am a citizen of the United States and reside at 1380 Outlook Drive West, Mountainside, NJ 07092.
2. I received a BA degree in Biochemistry and Biology from the University of Pennsylvania in 1976, a Master of Philosophy (M. Phil.) and a Ph.D. in Biomedical Sciences from the Mount Sinai School of Medicine of the City University of New York in 1982 and an M.D. degree from the Mount Sinai School of Medicine in 1983. I trained in Internal Medicine at the Montefiore Medical Center of the Albert Einstein School of Medicine from 1983 to 1985, as a Medical Staff Fellow at the National Heart, Lung and Blood Institute of the National Institutes of Health from 1985 to 1988, and as a fellow in Medical Oncology/Hematology at Memorial Sloan Kettering Cancer Center from 1988 to 1992. I was employed as an attending physician on the Autologous Bone Marrow Transplant Service at Memorial Sloan Kettering Cancer Center from 1992 to 1993. I have been employed at the University of Medicine and Dentistry of New Jersey-New Jersey Medical School as a faculty member from 1993 to the present time. The details of my education and professional history are set forth in my curriculum vitae, attached hereto as Exhibit A.
3. I have over 33 years experience in the fields of biomedical sciences and medicine.

4. I am the author or co-author of more than 36 scientific articles on the subjects of biology, biophysics and oncology. A list of these articles is set forth in my curriculum vitae, attached hereto. My current area of research involves dormancy and survival signaling in breast cancer micrometastases in the bone marrow and interaction of micrometastatic breast cancer cells with the bone marrow microenvironment.

5. I am an inventor of the subject matter disclosed and claimed in United States Patent Application Number 10/521,841 (hereinafter the '841 application).

Statements Regarding the Defects of Varner and Li et al.

6. I have read and discussed with counsel the Official Action dated April 24, 2009, received in connection with the '841 application. I understand the nature of the rejections made by the Examiner concerning Varner [United States Patent Number (USPN) 7,311,911] in view of Li et al. (United States Publication Serial Number 2004/0048312).

7. The Office Action acknowledges that Varner does not teach or suggest adjuvant therapy. As an expert in the field, I can confirm that there is no teaching in Varner that relates to an adjuvant setting. Indeed, as taught throughout Varner, the intended therapeutic purpose with regard to patients with cancer is to reduce or inhibit tumor angiogenesis. It is well understood in the field of clinical oncology that a therapeutic purpose directed to reducing or inhibiting tumor angiogenesis only pertains to a patient with detectable disease (i.e., a detectable tumor or tumors). In contrast, my invention relates to a method for treating a patient in an adjuvant setting, wherein the patient fails to exhibit signs of detectable disease. It is, therefore, apparent that the method of the present invention and that of Varner are directed to distinct patient populations.

8. In light of the above, the statements in the Office Action pertaining to Varner

allegedly teaching that administration to a subject can either be over a relatively short period of time or can be over a more prolonged period of time and that different therapeutic protocols can be used to achieve the most effective regimen are misapplied. In keeping with the teachings of Varner, such guidance only relates to a method for reducing or inhibiting angiogenesis for therapeutic purposes. Wherein the therapeutic purpose relates to the treatment of cancer in a patient, the intended purpose is to reduce or inhibit tumor angiogenesis. Thus, the teaching of Varner pertaining to treatment duration and therapeutic protocol would be understood by an ordinarily skilled practitioner to apply to treatment of a patient with detectable disease.

9. The Office Action looks to Li et al. for purportedly teaching adjuvant therapy. The Office Action concludes that the combined teachings of Varner and Li et al. would allegedly lead an ordinarily skilled practitioner to realize my invention. I disagree for a variety of reasons. To begin, the Li et al. patent application is directed in its entirety to integrin $\alpha v \beta 6$ and its role in human cancers and a monoclonal antibody (mBLA3) specific for integrin $\alpha v \beta 6$. As shown in Figure 1 of Exhibit B (attached), I assessed and did not observe an increase in the expression of either αv or $\beta 6$ in the dormant (growth arrested) breast cancer cells analyzed as taught in the present specification. For the record, Figure 1 of Exhibit B is identical to that of Figure 5A or 5B of the instant specification (United States Publication Number 2006/0035825), except that the arrows have been altered to be directed to the positions corresponding to αv and $\beta 6$ mRNA on the microarray. Furthermore, Figure 13A of the instant specification demonstrates clearly and unambiguously that adhesion of dormant growth arrested breast cancer cells to fibronectin, a ligand for both integrins $\alpha 5 \beta 1$ and $\alpha v \beta 6$, depends on integrin $\alpha 5$ but is unaffected by blocking antibody to integrin αv . This complements the gene array expression data demonstrating a lack of expression of integrin $\alpha v \beta 6$ in dormant breast cancer cells with a functional assay demonstrating a dependence of survival on integrin $\alpha 5$, which is contrasted with a complete lack of dependence on integrin αv . These results demonstrate unequivocally that αv and $\beta 6$ do not play a significant role in the survival of dormant (growth arrested) breast cancer cells in the bone marrow microenvironment.

10. Moreover, in view of the teaching in the instant specification regarding the identity of the microarray used for the analysis presented in Figures 5A and 5B (see, for example, paragraph [0031]), an ordinarily skilled practitioner would have been able to identify which spots on the grid correspond to αv and $\beta 6$ mRNA on the microarray should such a practitioner have been motivated to investigate the expression of these mRNAs in the context of dormant breast cancer cell micrometastases. Indeed, I perform similar evaluations on microarray analyses published in the literature as a matter of routine practice. In short, all that an ordinarily skilled practitioner requires in this regard is the supplier and product name/catalog number of the microarray, because the identity of the particular positions/spots on the array is publicly available. Thus, in the unlikely event that an ordinarily skilled practitioner might have thought to combine the teachings of Varner and Li et al., the microarray data (Figures 5A and 5B) and the functional data (Figure 13A) presented in the instant specification would have discouraged such a practitioner from pursuing the combination. My results suggest that such a combination of teachings would not have had a reasonable expectation for success because $\alpha v\beta 6$ integrin is not expressed in dormant breast cancer cell micrometastases

11. The results presented in Figure 1 and general knowledge in the field also underscore the fact that integrins represent a very diverse family of proteins. Integrins exhibit dissimilar functions and such functions are, in turn, modified differentially in the context of different cellular environments. Thus, an ordinarily skilled practitioner would appreciate that what is determined to be true for one integrin cannot accurately be extrapolated to apply to any other integrin. That being said, there is no scientific basis for imagining that teaching the use of antibodies to a particular integrin in an adjuvant setting extends to the use of antibodies to any other integrin in any adjuvant setting. An ordinarily skilled practitioner would appreciate that in the absence of evidence indicating which integrin or integrins are relevant in a particular clinical setting with respect to expression and activity, there is no way to predict whether antibodies to a particular integrin will have any clinical utility. Furthermore, my data demonstrate that antibodies to $\alpha v\beta 6$ integrin are unlikely to have any clinical utility in the context of breast cancer

cell micrometastases in the bone marrow because $\alpha v \beta 6$ integrin is not expressed on these cells. See Exhibit B.

12. Moreover, the literature appears to show a consensus that $\alpha v \beta 6$ increases with carcinogenesis in most primary tumors and some metastases, but primarily in squamous cell carcinomas, as well as in colon and ovarian epithelial cells. Expression appears to increase with cell crowding. There are no data on expression in breast cancer metastases. In the paper by Van Aarsen et al. (submitted previously), only a minority of primary breast carcinomas express this fibronectin binding integrin. Accordingly, since there are no data on metastasis, no significant role attributed to primary breast tumors, no evidence of expression in metastatic breast cancer cells and no evidence of an increase in dormant cells, there appears to be no prior data supporting a role for integrin $\alpha v \beta 6$ in survival of dormant micrometastatic breast cancer cells in the bone marrow. The literature, therefore, fails to provide support for a role for integrin $\alpha v \beta 6$ as a target for adjuvant therapy.

13. In summary, Varner teaches therapeutic regimens that inhibit angiogenesis and call for inhibition of $\alpha 5 \beta 1$ integrin signaling, but Varner fails to teach adjuvant therapy. The Li et al. application mentions adjuvant therapy in passing, but is focused in its entirety on $\alpha v \beta 6$ integrin and its role in human cancers and a monoclonal antibody (mBLA3) specific for $\alpha v \beta 6$ integrin. An ordinarily skilled practitioner would appreciate that $\alpha 5 \beta 1$ integrin and $\alpha v \beta 6$ integrin are functionally disparate integrins and would not, therefore, consider it obvious to apply teachings pertaining to one integrin to that of the other. The literature, moreover, fails to teach or suggest any role for $\alpha v \beta 6$ integrin in growth arrested cancer cells in general or growth arrested breast cancer cells in particular, nor any evident role in metastatic or micrometastatic breast cancer. In contrast, the literature affirms a role for $\alpha v \beta 6$ integrin in rapidly proliferating cancer cells (i.e., non-dormant cancer cells). My data demonstrate that $\alpha v \beta 6$ integrin is not expressed in dormant (growth arrested) breast cancer cells in the bone marrow microenvironment. See Figures 5A, 5B, and 13A of the application as filed and Figure 1 of Exhibit B. Taken together, these facts

would dissuade an ordinarily skilled artisan from combining the teachings of Varner and Li et al. Indeed, the facts in combination teach away from the presently claimed invention.

14. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-referenced application or any patent issued thereon.

9/15/09
DATE



NAME ROBERT WIEDER, MD, PhD

EXHIBIT A

DATE 9/15/09

CURRICULUM VITAE

NAME: Robert Wieder

HOME ADDRESS: 1380 Outlook Drive West
Mountainside, New Jersey 07092 Telephone: 908-377-1465

OFFICE ADDRESS: UMDNJ-New Jersey Medical School
Cancer Center H1216 Telephone: (973) 972-4871
185 South Orange Avenue E-mail: wiederro@umdnj.edu
Newark, NJ 07103

1. EDUCATION:

a. Undergraduate:

University of Pennsylvania, Philadelphia, PA
1976 B.A. in Biochemistry and Biology

b. Graduate and Professional:

Mount Sinai School of Medicine of the City University of NY, New York, NY
1982 M.Phil. in Biomedical Sciences
1982 Ph.D. in Biomedical Sciences
1983 M.D.

2. POSTDOCTORAL TRAINING

a. Internship and Residencies:

1983-1985 Intern and Junior Resident, Internal Medicine, Montefiore Hospital
Medical Center, Albert Einstein College of Medicine, Bronx, NY
1985-1986 Medical Staff Fellow, Clinical Associate, National Heart, Lung and Blood
Institute, NIH, Bethesda, MD
1988-1992 Fellow, Medical Oncology/Hematology, Memorial Sloan-Kettering
Cancer Center, New York, NY

b. Research Fellowships:

1986-1988 Medical Staff Fellow, Laboratory of Molecular Hematology,
National Heart, Lung and Blood Institute, NIH, Bethesda, MD

3. MILITARY

None

4. LICENSURE

- a. N.J. Medical License: MA 60226, 1993
- b. Other State Medical License: N.Y., 159293, 1984

5. CERTIFICATION

Board Certified: Internal Medicine, #107202
Medical Oncology, #107202

6. NARCOTICS CERTIFICATION

U.S. BW 3903261
N.J. DO 63847

7. UNIVERSITY APPOINTMENTS

1992-1993 Instructor, Cornell University Medical College, New York, NY
1992-1993 Instructor, Department of Medicine, Memorial Sloan-Kettering Cancer Center, New York, NY
1993-2000 Assistant Professor, Department of Medicine, UMDNJ-New Jersey Medical School
1997-present Assistant Professor, Department of Microbiology and Molecular Genetics, UMDNJ-New Jersey Medical School
1997-present Assistant Professor, Department of Microbiology and Molecular Genetics, UMDNJ-Graduate School of Biomedical Sciences
1996-1999 Interim Director, Division of Oncology, Department of Medicine, UMDNJ-New Jersey Medical School
1999-2001 Interim Director, Division of Oncology/Hematology, Department of Medicine, UMDNJ-New Jersey Medical School
1998-2001 Associate Director, Clinical Research, UMDNJ-Cancer Center/ Newark
1997-present Research Associate Member, Cancer Institute of New Jersey
2000-present Associate Professor, Dept. of Medicine, UMDNJ-NJ Medical School
2005-present Director, Clinical Research Office, UMDNJ-NJ Medical School/University Hospital Cancer Center
2009-present Co-Medical Director, Center for Clinical and Translational Science, UMDNJ-NJ Medical School

8. HOSPITAL APPOINTMENTS

1983-1985 Montefiore Hospital, Medical Center, Bronx, NY, Housestaff
1983-1985 North Central Bronx Hospital, Bronx, NY, Housestaff
1985-1988 NIH Clinical Center, Medical Staff Fellow
1988-1992 Memorial Sloan-Kettering Cancer Center, New York, NY, Fellow, Medical Oncology/Hematology
1988-1992 Cornell Medical Center, New York, NY, Fellow, Medical Oncology/Hematology
1992-1993 Memorial Sloan-Kettering Cancer Center, Attending Physician Leukemia Service, Autologous Bone Marrow Transplant Unit
1994-present UMDNJ-University Hospital, Medical Oncology/Hematology

9. OTHER PROFESSIONAL POSITIONS AND MAJOR VISITING APPOINTMENTS

July-Sept., 1987 Special Fellow, Adult Bone Marrow Unit, Memorial Sloan-Kettering Cancer Center, New York, NY

10. AWARDS AND HONORS

1976	B.A. Cum Laude and Honors in Biochemistry
1980	NIH Medical Student Research Fellow
1981-1982	Mount Sinai Medical Scientist Fellow
1988-1989	American Cancer Society Clinical Oncology Fellow
1990-1991	Mortimer J. Lacher Fellow
1990-1992	Memorial Sloan-Kettering Cancer Center Clinical Scholars Biomedical Research Fellow
1990-1992	Charles A. Dana Fellow
1992	ASCO Travel Award
1994	Foundation of the University of Medicine and Dentistry of New Jersey Grant Award
1994	US Army Breast Cancer Research Prog. Career Development Award
1998	State of New Jersey Commission on Cancer Research Outstanding Breast Cancer Researcher Award
2001	State of New Jersey Commission on Cancer Research Service Recognition Award
2001	UMDNJ-New Jersey Medical School Faculty Association Clinical Sciences Faculty of the Year

11. BOARDS OF DIRECTORS/TRUSTEES none

12. MAJOR COMMITTEE POSITIONS AND MAJOR VISITING APPOINTMENTS

Extraintitutional

1995-1996	Member, Special Awards Committee, American Soc. Clinical Oncology
1995-pres.	NJ State Comm. on Cancer Research Breast Cancer Advisory Board, Chair 1998-2001, 2006-present
1996-2005	Program Review Committee, Annual New Jersey Breast Cancer Research Symposium
1997	Program Review Committee, Annual Scientific Retreat of the Cancer Institute of New Jersey and The New Jersey State Commission on Cancer Research
1997-2004	Cancer Institute of New Jersey Protocol Advisory Committee
1999	Research Planning Committee, Annual Scientific Retreat of the Cancer Institute of New Jersey and The New Jersey State Commission on Cancer Research
1999-2000	Member, State of New Jersey Department of Health and Senior Services <u>Circle of Friends</u> Advisory Board
2002-present	Extraintitutional Member, Mount Sinai School of Medicine Institutional Biosafety Committee
2003	Program Review Committee, Annual Scientific Retreat of the Cancer

Institute of New Jersey and The New Jersey State Commission on
Cancer Research
2009-present Cancer Institute of New Jersey Clinical Trial Network Steering
Committee

Institutional

NIH

1886-1988 NIH Bioethics Liaison Group
1987 Consultant, Working Group on General Information, Human Gene
Therapy Subcommittee, NIH Recombinant DNA Advisory Committee.

UMDNJ

1993-1997 Medical School Admissions Committee
1994-present M.D./Ph.D Committee, UMDNJ-NJMS/Graduate School Biomedical
Sciences, Member Program Committee and Advisory Council, Associate
Director (Clinical) - 1998-2003
1994-1995 Dean's Search Committee for Chair of Biochemistry and Molecular
Biology, New Jersey Medical School
1994-1995 Search Committee for Director of Oncology/Hematology, UMDNJ-
NJ Medical School
1993-1997 NJMS Research Office Summer Student Research Program Advisory
Comm.
1993-1996 NJMS Dept. of Medicine Committee on Medicare Patient Outcomes
Research
1995-present NJMS Faculty Investigator Group
1995 Search Committee for Director of Oncology, Beth Israel Medical Center,
Newark, NJ,
1995-1997 Dean's Biomedical Research Support Committee
1995-2001 Founding Member Internal Medicine Resident Research Committee
1995-1996 Dean's Self-Study Task Force, Med. School Clin. Science Depts.
Committee
1995-2000 Screening Access of Value to Elderly Women Coalition (SAVE),
Women's Wellness Center, UMDNJ-New Jersey Medical School
1996-2003 UMDNJ/University Hospital Oncology Committee
1996 Dean's Committee on the Oncology Program
1996-2000 Dean's Research Advisory Group
1996-2000 IAMS Research Planning Committee
1996-2000 UMDNJ Committee on Bloodless Surgery and Medicine
1997-1998 Internal Medicine Residency Curriculum Committee
1997-1998 Dean's Committee on Research Space Allocation at NJ Medical School
1997-1998 Steering Committee, the Cancer Center at New Jersey Medical School
1998 Dean's Space Advisory Committee
1998-2000 NJMS Research Planning and Priorities Committee
1998-1999 Cancer Center Executive Committee
1999-2001 NJMS cancer education program committee
1999-2001 UMDNJ-UH Pain Management Committee
1999-2000 UMDNJ-UH Cancer Program Survey Team 2000
2000-2001 Cancer Center Steering Committee

2001 Ad hoc Searle, Pew and Sinsheimer Scholars review committees
2001 UMDNJ-NJMS Dept. Medicine Retreat Research Planning Committee
2001-2003 UMDNJ-NJMS Department of Medicine Research Committee
2001-2004 Dean's Search Committee for Chair of Pediatrics, NJ Medical School
2002-2006 UMDNJ-NJMS Cancer Center Animal Facility Advisory Committee
2003-2007 UMDNJ-NJMS Basic Science/Translational Task Force
2003-present UMDNJ-Newark Campus Institutional Review Board
2004-2005 UMDNJ Research Conflicts of Interest Committee
2004 NJMS/UH Cancer Center Director Search Committee
2004-present NJMS Cancer Education Program Executive Committee
2004-present NJMS Biomedical Research Support Committee
2004-present NJMS-UH Cancer Center Committee for Basic and Translational Research
2004-2005 UMDNJ-NJMS Search Committee for Faculty of Biostatistics
2005 UMDNJ-NJMS/UH Cancer Center Search Committee for Chief Operating Officer
2005-present NJMS-UH Cancer Center Faculty Search Committee
2007 Coordinator of NJMS-UH Cancer Center Science Grand Rounds
2007-2008 UMDNJ-NJMS Faculty Committee on Appointments and Promotions
2009-present Member, Clinical Research Leadership Group, UMDNJ-NJMS Center for Clinical and Translational Science

13. MEMBERSHIPS, OFFICES AND COMMITTEE ASSIGNMENTS IN PROFESSIONAL SOCIETIES

1992 Member, The American Society of Hematology
1994 Member, American Society of Clinical Oncology;
Special Awards Committee (95-96)
1994 Member, American Association for Cancer Research
1995 Member, American Society for Blood and Marrow Transplantation
1997 Member, The Harvey Society
2002 Member, European Society of Medical Oncology
2005 Member, Metastasis Research Society

14. MAJOR RESEARCH INTERESTS

- a. Dormancy and survival signaling in breast cancer
- b. Roles of retinoids and vitamin D analogues in breast cancer
- c. Gene therapy for treatment of cancer
- d. Clinical trials in Oncology in minority patients

15. GRANT HISTORY

Past support

a. Principal investigator

Title: Clinical Oncology Fellowship #88-144.

Agency: American Cancer Society

Direct Costs: \$10,000.

Period: 7/1/88-6/30/89

Title: Training Grant #T32 CA-09512-07

Agency: NIH

Direct Costs: \$30,000.

Period: 7/1/89-6/30/90

Title: Biomedical Scholar Award

Agency: Memorial Sloan-Kettering Cancer Center

Direct Costs: \$60,000.

Period: 7/1/90-6/30/92

Title: Leukemia Research, unrestricted

Agency: United Food and Commercial Workers Union Leukemia Fund.

Direct Costs: \$ 5,000.

Period: 1995

Title: Apoptosis in breast cancer, unrestricted

Agency: Friends of Charity

Direct Costs: \$ 15,500.

Period: 1995

Title: Breast Cancer Research Symposium of New Jersey

Agency; New Jersey Commission on Cancer Research

Direct Costs: \$10,000.

Period: 1996

Title: Research grant: The Role of basic fibroblast growth factor in human breast cancer.

Agency: Foundation of the University of Medicine and Dentistry of New Jersey.

Direct Costs: \$ 48,900.

Period: 7/1/94-6/30/95 (extended without additional funds to 6/30/97)

Title: Career Development Award AIBS #200, DAMD17-94-J-4463:

The Role of basic fibroblast growth factor in human breast cancer.

Agency: DOD, U.S. Army Breast Cancer Research Program.

Direct Costs: \$ 200,000.

Period: 10/1/94-9/30/98

Title: Phase II study of the efficacy of Doxil (Doxorubicin HCl liposome injection, Sequus Pharmaceuticals Inc., Menlo Park, CA 94025) in stage IV breast cancer.

Agency: Sequus Pharmaceuticals, Inc., Menlo Park, CA

Direct Costs: \$ 14,100.

Period: 1997-1999

Title: Phase I/II trial of 13-cis-retinoic acid (Accutane), Paclitaxel (Taxol) and Carboplatin in recurrent of metastatic squamous cell carcinoma of the head and neck.

Agency: Bristol-Myers, Inc.

Direct Costs: \$ 46,059.

Period: 1997-1999

Title: Differentiation of Breast Cancer by Retinoids and Vitamin D₃

Agency: State of New Jersey Commission on Cancer Research

Direct Costs: \$ 45,455.

Period: 1998-2000

Title: A Phase I Study of Oral ILX 23-7553 Administered Daily × 5 Every 2 Weeks in Patients With Solid Tumors

Agency: Ilex Oncology

Direct Costs: \$ 52,800.

Period: 1999-2002

Title: Roles of all-*trans* retinoic acid and vitamin D₃ in potentiating cell death signaling by Taxotere in breast and prostate cancer

Agency: Aventis, Inc.

Direct Costs: \$ 133,500.

Period: 2000-2002

Title: Potentiation of Taxotere-induced cytotoxicity by flavopiridol in breast cancer cells

Agency: Aventis, Inc.

Direct Costs: \$ 98,464.

Period: 2002-2003

Title: Research grant: DAMD17-01-C-0343:

The Roles of FGF-2, TGF Beta, and TGF Beta Receptor 2 in Breast Cancer Dormancy.

Agency: DOD, U.S. Army Breast Cancer Research Program.

Direct Costs: \$ 230,509.

Period: 7/1/01-6/30/03

Title: The Role of Bone Marrow Stromal FGF-2 in Breast Cancer Dormancy.

Agency: State of New Jersey Commission on Cancer Research 02-1140-CCR-E0

Direct Costs: \$ 136,364. (Collaboration with Rider U.) Direct to our lab: \$68,182.

Period: 6/1/02-5/30/04

Title: Phase II Trial of 13-*cis* retinoic acid (Accutane), paclitaxel (Taxol) and paraplatin (Carboplatin) in invasive, recurrent or metastatic squamous cell carcinoma of the cervix

Agency: Bristol-Myers, Inc.

Direct Costs: \$ 122,946.

Period: 2001-2004

Title: Research grant: DAMD17-03-1-0524:

Overcoming Bone Marrow Stroma-Mediated Chemoresistance in Metastatic Breast Cancer Cells.

Agency: DOD, U.S. Army Breast Cancer Research Program.

Direct Costs: \$ 312,903.

Period: 7/1/03-6/30/06

Title: Phase II trial of Vesanoid (TRETINOIN, all-*trans* retinoic acid) and Taxol (Paclitaxel) in

patients with stage IV breast cancer

Agency: Bristol-Myers, Inc.

Direct Costs: \$ 70,000.

Period: 1999-2006

Title: Mechanisms involved in the treatment and prevention of breast cancer by 1,25-dihydroxyvitaminD₃

Co-equal PI: with Sylvia Christakos, Department of Biochemistry and Molecular Biology, UMDNJ-NJMS

Agency: NJMS-UH Cancer Center Research Grants Program

Direct Costs: \$80,000.

Period: 2006-2007

Title: Signal pathway activation signature of cisplatin resistance in head and neck cancer

Role: Co-equal PI (with Erik Cohen) 20% effort

Agency: Foundation of UMDNJ

Direct Costs: \$ 70,000.

Period: 2007-2008

Title: Effects of perscription coverage on control of cancer pain: 08-1096-CCR-EO

Role: PI 10% effort

Agency: New Jersey Commission on Cancer Research

Direct Costs: \$ 18,000.

Period: 2007-2008

Title: Elimination of dormant breast cancer cells by targeting survival signaling

Role: PI 10% effort

Agency: Ruth Estrin Goldberg Foundation

Direct Costs: \$ 25,000.

Period: 2008-2009

b. Co-Investigator:

Title: Summer Fellowship (with Karen J. Finnigan): The roles of basic FGF in breast cancer

Agency: New Jersey Commission on Cancer Research

Direct Costs: \$2,800.

Period: 7/1/94-8/31/94

Title: Outstanding Breast Cancer Research Fellowship (with Qin Wang): Modulation of apoptosis by basic FGF in breast cancer

Agency: State of New Jersey Commission on Cancer Research

Direct Costs: \$50,000.

Period: 9/5/97-9/4/99

Title: Post-Doctoral Supplement to NJCCR Breast Cancer Research Fellowship (Qin Wang)

Agency: Foundation of UMDNJ

Direct Costs: \$10,000.

Period: 9/5/97-9/4/99

Title: Community Cancer Screening for Black/Hispanic Women
Agency: Centers for Disease Control and Prevention
Direct Costs: \$5,000.
Period: 9/30/99-9/29/00

Title: Summer Fellowship (with Ilan Seth Weinberg): Eligibility screening for a Phase I colon cancer vaccine protocol

Agency: New Jersey Commission on Cancer Research
Direct Costs: \$2,800.

Period: June-August, 2000

Title: Summer Fellowship (with Jeaudine Evadne Bontemps): NSABP P-2 Trial: Study of Tamoxifen and Raloxifene (STAR) for the prevention of breast cancer

Agency: New Jersey Commission on Cancer Research
Direct Costs: \$2,800.

Period: June-August, 2000

Title: Summer Fellowship (with Michael Lindy): Overcoming Breast Cancer Dormancy in the Bone Marrow Microenvironment

Agency: New Jersey Commission on Cancer Research
Direct Costs: \$2,800.

Period: June-August, 2003

Title: Summer Fellowship: Mediation of Survival Signaling in Dormant Breast Cancer Cells through PI3 kinase and Rho

PI: Bryan Benn

Agency: New Jersey Commission on Cancer Research
Direct Costs: \$2,800.

Period: June-August, 2004

Title: Inhibition of Breast Cancer Growth by Vitamin D

PI: Sylvia Christakos, Department of Biochemistry and Molecular Biology, UMDNJ-NJMS
Agency: AHEPA Foundation

Direct Costs: \$10,000.

Period: 2004-2005

Title: Summer Fellowship (with Joanna Sesti): Role retinoic acid in disrupting survival signaling in dormant breast cancer cells

Agency: New Jersey Commission on Cancer Research
Direct Costs: \$2,800.

Period: June-August, 2006

Title: Potentiation of radiation-induced cytotoxicity in 1483 head and neck squamous cell carcinoma by COX-2 inhibition

Co-PI: Erik G. Cohen, Department of Surgery, UMDNJ-NJMS

Agency: Foundation of UMDNJ

Direct Costs: \$50,000.

Period: 2004-2006

Title: Signal pathway activation signature of cisplatin resistance in head and neck cancer

Role: Joint Co-PI with Erik Cohen 20% effort

Agency: Foundation of UMDNJ

Direct Costs: \$ 70,000.

Period: 2007-2008

Title: Role of Integrin Signaling in Resistance to Chemotherapy in Head and Neck Squamous Cell Carcinoma

Role: Co- PI (with Erik Cohen) 10% effort

Agency: Ruth Estrin Goldberg Foundation

Direct Costs: \$ 25,000.

Period: 2007-2008

Present support

a. Principal investigator

Title: Use and evaluation of an ethnically-matched patient navigator to increase minority patient recruitment to breast cancer clinical trials

Role: PI 10% effort

Agency: The Susan G. Komen Breast Cancer Foundation of Northern New Jersey

Direct Costs: \$195,000.

Period: 2007-2010

Title: Cancer Center Patient Navigator Program

Role: PI 20% effort

Agency: C.R. Bard Foundation

Direct Costs: \$ 50,000.

Period: 2007-2009

Title: Research grant: W81XWH-09-1-0119

Reactivation of Breast Cancer Micrometastases by Senescent Bone Marrow Stroma (Human)

Agency: DOD, U.S. Army Breast Cancer Research Program.

Role: PI 15% effort

Direct Costs: \$ 375,000.

Period: 7/1/09-6/30/12

Title: Reactivation of breast cancer micrometastases by senescent bone marrow stroma

Role: PI 20%

Agency: NJMS Dean's Annual Bridge Grant Program

Direct Costs: \$25,000.

Period: 2008-2010

Title: Research grant: 1 R21 CA142537-01A1

Reactivation of Breast Cancer Micrometastases by Senescent Bone Marrow Stroma (Murine)

Agency: NCI

Role: PI 11.6% effort

Direct Costs: \$ 242,000.

Period: 7/1/09-6/30/11

Title: Minority Breast Cancer Navigator Program

Role: PI 10%

Agency: Susan G. Komen for the Cure of Northern New Jersey

Direct Costs: 16,000.

Period: 2009-2010

Title: UMDNJ-NJMS/UH Cancer Center Clinical Research Program

Role: PI 15%

Agency: New Jersey Commission on Cancer Research - New Jersey Cancer Research Development Award

Direct Costs: \$ 427,595.

Period: 2009-2010

Title: Research grant: 1U10CA128506-01A1

Minority-Based CCOP at UMDNJ-NJ Medical School/University Hospital Cancer Center

Agency: NCI

Role: PI 30% effort

Direct Costs: \$ 1,188,911.

Period: 8/24/09-5/31/12

b. Co-investigator

-

Provisional Patent disclosures filed

- 2002 Alpha5 Beta1 and its Ability to Regulate the Cell Survival Pathway 60/396,482
Application filed 2003 - 601-1-134PCT
European Patent filing 7/16/03 Application/Patent no. 03799816.8-2403-US0321954
- 2003 Development of microfluidics technology to map cell surface protein signatures for use in laboratory investigations, diagnosis, prognosis and treatment of disease. – in collaboration with Sarnoff Corporation, Princeton, NJ
- 2004 Molecular and Cellular Retardation Methods and the Encounter, or Interaction, Complex. – in collaboration with Sarnoff Corporation, Princeton, NJ

16. MAJOR TEACHING EXPERIENCE

- 1975-76 Teaching Assistant, Organic Chemistry Laboratory, Department of Chemistry, University of Pennsylvania, Philadelphia, PA.
- 1993-1998 Participated in Dept. Microbiology and Mol. Genetics Mol. Biology Journal Club

1993	Lectured in the New Jersey Medical School Immunology course
1994-1996	Supervised Clinical Oncology Fellows on the wards and in clinic
1994-1996	Conducted Clinical Oncology Journal Club
1994-present	Lectured to New Jersey Medical School Internal Medicine Residents
1994-present	Lectured annually in the New Jersey Medical School Introduction to Clinical Sciences course, Participated in physical diagnosis sessions
1994-present	Lectured annually in Medical Student Summer Cancer Biology Research Program
1995, 1997	Lectured in the UMDNJ-Graduate School of Biomedical Sciences Biology of Human Tumors Course,
1995-2001	Lectured annually in the New Jersey Graduate School Microbial Genetics II Course
2001	UMDNJ-NJMS Mini Med School - How Cancer is Treated
2001, 2003, 2005	Lectured in the UMDNJ-Graduate School of Biomedical Sciences Molecular and Immunopathologic Mechanisms of Cancer
2003	Lectured in Oncology Nurses training course, UMDNJ-University Hospital
2003	Lectured in UMDNJ-NJMS Medical Residents Conference, UMDNJ-UH
2004	Lectured in UMDNJ-NJMS Physical Medicine and Rehabilitation Residents Conference, Kessler Institute for Rehabilitation
2006	Lectured in UMDNJ-NJMS Medical Residents Conference, UMDNJ-UH
2006	Medical Student Transition Curriculum presentation on CBCs
2008	Lectured in UMDNJ-NJMS Medical Residents Conference, UMDNJ-UH
2008, 2009	Course Director, Principles of Clinical and Translational Research in Oncology, UMDNJ-GSBS GSND 5235Q
2009	Lectured in UMDNJ-NJMS Medical Residents Conference, UMDNJ-UH

MEMBER GRADUATE THESIS OR EXAMINATION COMMITTEES

Jennifer B. Jones (Department of Laboratory Medicine and Pathology, UMDNJ-Graduate School of Biomedical Sciences)

Jackie Washington (Department of Microbiology and Molecular Genetics, UMDNJ-Graduate School of Biomedical Sciences)

Daniel Aviv (Department of Microbiology and Molecular Genetics, UMDNJ-Graduate School of Biomedical Sciences)

Xuening Wang (Department of Laboratory Medicine and Pathology, UMDNJ-Graduate School of Biomedical Sciences)

Qing Mei Wang (Department of Laboratory Medicine and Pathology, UMDNJ-Graduate School of Biomedical Sciences)

James Nugent (Department of Microbiology and Molecular Genetics, UMDNJ-Graduate School of Biomedical Sciences)

Achal Trivedi (Department of Microbiology and Molecular Genetics, UMDNJ-Graduate School of Biomedical Sciences)

Roman Wernyj (Department of Biochemistry and Molecular Biology, UMDNJ-Graduate School of Biomedical Sciences)

Jennifer Czarneski (Department of Laboratory Medicine and Pathology, UMDNJ-Graduate School of Biomedical Sciences)

Sahba Kianifard (Department of Microbiology and Molecular Genetics, UMDNJ-Graduate School of Biomedical Sciences)
Melanie K. Lenahan (Department of Microbiology and Molecular Genetics, UMDNJ-Graduate School of Biomedical Sciences)
Kathy Piparo (Department of Biochemistry and Molecular Biology, UMDNJ-Graduate School of Biomedical Sciences)
Megan Fredericks (Department of Biochemistry and Molecular Biology, UMDNJ-Graduate School of Biomedical Sciences)
Wei Bu (Department of Microbiology and Molecular Genetics, UMDNJ-Graduate School of Biomedical Sciences)
Anoop Kavirayani (Department of Microbiology and Molecular Genetics, UMDNJ-Graduate School of Biomedical Sciences)
Pedro L. Rodriguez (Biomedical Sciences Program, UMDNJ-Graduate School of Biomedical Sci.)
Shan Jiang (Department of Biochemistry and Molecular Biology, UMDNJ-Graduate School of Biomedical Sciences)
Zhaoyu Sun (Biomedical Sciences Program, UMDNJ-Graduate School of Biomedical Sci.)
Gwen Mahon (Biomedical Sciences Program, UMDNJ-Graduate School of Biomedical Sci.)
Edward Garay (Biomedical Sciences Program, UMDNJ-Graduate School of Biomedical Sci.)
Ethan Fitzpatrick (Biomedical Sciences Program, UMDNJ-Graduate School of Biomedical Sci.)
Ahmet Tonceroglu (Biomedical Sciences Program, UMDNJ-Graduate School of Biomedical Sci.)
Xiangwen Chen (Department of Laboratory Medicine and Pathology, UMDNJ-Graduate School of Biomedical Sciences)
Crystal DiCosmo (Department of Laboratory Medicine and Pathology, UMDNJ-Graduate School of Biomedical Sciences)

TRAINING SUMMER AND ROTATING STUDENTS

1994 Karen Finnigan
- won first prize in Summer Student Cancer Research Symposium
- won The Research Award for Scientific Excellence at the New Jersey State Commission on Cancer Research Annual Research Symposium, 1995
1994 Paul Maloof
1995 John Chung
1995 Daniel Fulop
1996 Christine Torigian
1996 Michelle A. Fanale
- first prize, Summer Student Cancer Research Symposium
- second prize, Annual NJMS Summer Student Res. Symp. (highest allowed)
- first prize, First UMDNJ Statewide Med. Student Resch. Competition, 1997
- Went on to Medical Oncology Fellowship at MD Anderson Cancer Center
1996 Annie Lin
1997 Mark Solomon
1997 Myrna S. Uytingco
- won second prize in Summer Student Cancer Research Symposium
1997 Joseph Golowa
1997 Renato Apolito

- won first prize in NJMS Summer Student Cancer Research Symposium
- 1999 Lydia Choi
 - selected as 1 of 40 students nationally for oral presentation at The National Student Research Forum, University of Texas Medical Branch, Galveston, TX
 - won The National Student Research Forum Oncologic Research Award,
- 2000 - won the Gallo Research Award for Scientific Excellence, 2000 Annual Retreat on Cancer Research in New Jersey, CINJ and the NJCCR
- 2004 - Went on to Cancer Research Fellowship at Sloan Kettering
- 1999 Elizabeth Scheff
 - won first prize in NJMS Summer Student Cancer Research Symposium
 - won first prize in NJMS Summer Student Research Symposium
 - selected as 1 of 40 students nationally for oral presentation at The National Student Research Forum, University of Texas Medical Branch, Galveston, TX
- 2000 Ilan Seth Weinberg
- Jeaudine Evadne Bontemps
- Mateusz Opyrchal (MD/PhD rotation)
- Jason Solomon
- 2001 Wei Bu (PhD rotation)
- 2001 Judith Barrios (PhD rotation)
- 2002 Michael Lindy - won Award for Scientific Excellence at the CINJ-New Jersey State Commission on Cancer Research Annual Retreat, 2002
- 2002 Ankoor Shah
 - won travel award to National Meeting in NJMS Summer Student Cancer Research Symposium
- 2003 Vineetha Joseph
 - won book award in NJMS Summer Student Cancer Research Symposium
- 2003 Michael Lindy -
 - won travel award to National Meeting in NJMS Summer Student Cancer Research Symposium
 - selected as 1 of 40 students nationally for oral presentation at The National Student Research Forum, Univ. of Texas Medical Branch, Galveston, TX
- 2004 Mark Solomon
 - won book award in NJMS Summer Student Cancer Research Symposium
- 2004 Bryan Benn – MD/PhD student
 - won book award in NJMS Summer Student Cancer Research Symposium
- 2005 Ethan Fitzpatrick (PhD rotation)
- 2005 Sylvia Vasquez
- 2006 Joanna Sesti
- 2006 Ahmet Tunceroglu (MD/PhD rotation)
- 2006 Aaron Rockoff (with Dr. Christakos, Biochemistry)
- 2007 Tara Tendler

TRAINING POST-DOCTORAL FELLOWS

1995-2000 Qin Wang, MD

- won The New Jersey Research Award for Scientific Excellence (Smith-Kline Beecham Oncology, 1997)

- won New Jersey Cancer Commission Outstanding Breast Cancer Research Post-Doctoral Fellowship, 1997
- won Gallo Research Award for Scientific Excellence at the New Jersey State Commission on Cancer Research Annual Retreat, 1999, 2000
- 2001-2002 Petra Archibald, PhD
 - won The Gallo Research Award for Scientific Excellence at the New Jersey State Commission on Cancer Research Annual Retreat, 2001
 - won the 2001 American Association for Cancer Research Minority Scholars in Cancer Research Award
 - won the 2001 American Association for Cancer Research-Inglennook Vineyards Scholar-in-Training Award
- 2001-2002 Rachna Chandra, PhD
- 2003 Monika Boots, PhD

TRAINING GRADUATE STUDENTS

- 2002-2009 Judith Barrios (PhD)
- 2007-2008 Christopher K. Hansen (MS)

TRAINING FACULTY

- 2004-2006 Mentor for ASCO Young Investigator Award to Eric Cohen, MD, Assistant Professor, Dept. of Surgery, UMDNJ-NJMS

PROFESSIONAL ACTIVITIES

- 1988 Speaker: ZWO/TNO/NIH Symposium on Factors and Vectors in Hemopoiesis, The Hague, The Netherlands. Title: Use of retrovirally-mediated gene transfer for gene therapy in ADA deficiency.
- 1992 Speaker: American Society of Clinical Oncology, San Diego, CA. Title: Retroviral gene transfer of the hbFGF gene in human stroma.
- 1992 Speaker: International Society of Hematology, Providence, RI. Title: Cycle-activation of high proliferative potential cells (HPPC) in mice administered high doses of cytosine arabinoside (Ara-C).
- 1994 Speaker: American Society of Clinical Oncology, Dallas, TX. Title: MCF7 human breast cancer cells are negatively regulated by overexpression of basic fibroblast growth factor (bFGF).
- 1994-2006 Speaker, approx. 2 times/year UMDNJ-University Hospital Tumor Conference
- 1995 Speaker: Fourth International Conference on Gene Therapy of Cancer, San Diego, Ca. Title: Overexpression of retrovirally transduced basic FGF in MCF-7 human breast cancer cells downregulates Bcl-2 and sensitizes cells to chemotherapy-induced apoptosis.
- 1996 Speaker: First Annual New Jersey Breast Cancer Research Symposium, Rider University, Lawrenceville, NJ. Title: Basic FGF causes growth arrest in MCF-7 human breast cancer cells while inducing both mitogenic and inhibitory G₁ events.
- 1997 Speaker: Second Annual New Jersey Breast Cancer Research Symposium, UMDNJ-Robert Wood Johnson Medical School, New Brunswick, NJ. Title: 1,25-Dihydroxyvitamin D₃ and all-*trans* retinoic acid sensitize breast cancer cells to the effects of chemotherapeutic agents.
- 1998 Speaker at Cancer Institute of New Jersey Protocol Advisory Committee meeting

- 1998 Plenary Session Speaker at The Annual Retreat on Cancer Research in New Jersey
- 1999 Session Speaker at The Annual Retreat on Cancer Research in New Jersey
- 1999 Plenary Session Speaker, The Third New Jersey Breast Cancer Research Symposium
- 1999 Speaker, ACS/Cancer Care/CINJ/NJCCR/NJHD/St. Barnabas Hosp. Conference on Critical Decisions in Cancer for the 21st Century, Iselin NJ,
- 2000 Plenary Session Speaker, The Department of Defense Breast Cancer Research Program Meeting, "Era of Hope". Atlanta, GA, June 2000
- 2001 Speaker at Cancer Institute of New Jersey Protocol Advisory Committee meeting
- 2001 Speaker at the New Jersey State Commission on Cancer Research Symposium, "Sharing Perspectives on Cancer Research: Cancer Researchers Reach Out", Rider University, Lawrenceville, NJ
- 2002 Session Chair, Transcriptional regulation and oncogenesis/molecular mechanisms of tumor growth. Annual Retreat on Cancer Research in NJ, The Cancer Institute of NJ and the NJ State Commission on Cancer Research.
- 2006 Session Chair and Speaker, 10th Anniversary of the New Jersey Breast Cancer Research Fund Symposium

Seminars Given:

- 1993 Division of Hematologic Oncology, Memorial Sloan-Kettering Cancer Center, NY
- 1993 Department of Microbiology and Molecular Genetics, UMDNJ-NJ Medical School
- 1994 Department of Medicine Research Seminar, UMDNJ-NJ Medical School
- 1994 Hematology/Oncology Grand Rounds, East Orange Veterans Administration Hospital
- 1995 Hematology/Oncology Grand Rounds, New York Medical College
- 1995 Department of Laboratory Medicine and Pathology, UMDNJ-NJ Medical School
- 1996 The Center for Laboratory Investigation, UMDNJ-NJ Medical School
- 1996 Department of Surgery Research Conference, UMDNJ-NJ Medical School
- 1996 Department of Surgery Grand Rounds, UMDNJ-New Jersey Medical School
- 1997 Speaker, UMDNJ-NJMS Summer Student Cancer Research Symposium
- 1997 Department of Medicine Research Seminar, UMDNJ-NJ Medical School
- 1998 Hematology/Oncology Grand Rounds, East Orange Veterans Administration Hospital
- 1998 Keynote Address, UMDNJ-NJMS Summer Student Cancer Research Symposium
- 1998 Department of Obstetrics and Gynecology Grand Rounds, UMDNJ-NJ Med. School
- 1999 Department of Obstetrics and Gynecology Resident Conference, UMDNJ-NJMS
- 1999 Department of Medicine Grand Rounds, East Orange Veterans Administration Hosp.
- 2000 Speaker, UMDNJ-NJMS Summer Student Cancer Research Symposium
- 2000 Department of Medicine Grand Rounds, UMDNJ-New Jersey Medical School
- 2000 Department of Microbiology and Molecular Genetics, UMDNJ-NJ Medical School
- 2001 Department of Obstetrics and Gynecology Resident Conference, UMDNJ-NJMS
- 2001 Department of Anatomy, Cell Biology & Injury Sciences Res. Seminar UMDNJ-NJMS
- 2001 Speaker at Cancer Institute of New Jersey SPORE project seminar series
- 2001 Speaker, UMDNJ-NJMS Summer Student Cancer Research Symposium
- 2001 Division of Urology, Dept. of Surgery Grand Rounds, UMDNJ-NJ Med. School
- 2001 Department of Medicine Research Seminar, UMDNJ-New Jersey Medical School
- 2002 Division of Endocrinology, Dept. Medicine Research Seminar, UMDNJ-NJMS
- 2002 Speaker, UMDNJ-NJMS Summer Student Cancer Research Symposium
- 2003 Speaker, UMDNJ-NJMS Summer Student Cancer Research Symposium

- 2003 Speaker at Cancer Institute of New Jersey breast cancer seminar series
- 2003 Seminar speaker at Rider University Department of Biology
- 2004 Research seminar, UMDNJ-University Hospital Tumor Board
- 2004 Speaker, UMDNJ-NJMS MD/PhD Student Research Seminar
- 2004 Speaker, UMDNJ-NJMS Summer Student Cancer Research Symposium
- 2004 Speaker Governor's School Students Cancer Biology Course
- 2005 Speaker, UMDNJ-NJMS Biomedical Sciences Program Research Seminar Series
- 2005 Seminar speaker at Rider University Department of Biology
- 2005 Speaker, Hematology/Oncology Research Conference, East Orange VA Hospital
- 2005 Speaker, Division of Endocrinology Research Conference, UMDNJ-NJMS
- 2006 Speaker, Research Conference, Department of Medicine, UMDNJ-NJMS
- 2006 Overview of Paradigms for Clinical Research, UMDNJ-University Hospital Cancer Center Grand Rounds
- 2006 Speaker, Division of Endocrinology Research Conference, UMDNJ-NJMS
- 2007 Speaker, UMDNJ-NJMS MD/PhD Student Research Seminar
- 2007 Seminar speaker, Department of Biochemistry and Molecular Biology, UMDNJ-New Jersey Medical School
- 2007 Speaker, UMDNJ-NJMS Summer Student Cancer Research Symposium
- 2007 Speaker, UMDNJ-NJMS Summer Student Cancer Research Seminar Series
- 2008 Speaker, UMDNJ-NJMS Mini Med School
- 2008 Speaker, Cancer Institute of New Jersey Breast Cancer Program Seminar Series
- 2008 Speaker, UMDNJ-NJMS Summer Student Cancer Research Symposium
- 2008 Speaker, McNair Summer Student Scholars Program, Rider University, Lawrenceville, NJ
- 2008 Speaker, UMDNJ-NJMS Premed Honors Program
- 2009 Speaker, UMDNJ-NJMS Summer Student Cancer Research Symposium

Meeting Organizer:

- 1996 Co-chair: First New Jersey Breast Cancer Research Symposium
- 1999 Co-chair: Third New Jersey Breast Cancer Research Symposium

Manuscript reviewer:

Biochemical Pharmacology
Biochimica et Biophysica Acta
British Journal of Cancer
Cancer
Cancer Letters
Cancer Research
Clinical Cancer Research
Endocrinology
Experimental Cell Research
FEBS Letters
Journal of Biological Chemistry
Journal of Cellular Biochemistry
Journal of Cellular Physiology

Molecular Cancer Therapeutics
Molecular Pharmacology
Oncogene
Pharmacological Research

Grant reviewer

1994-2000	Foundation of UMDNJ
2000	Dutch Cancer Society (<i>ad hoc</i>)
2001	National Science Foundation (<i>ad hoc</i>)
2003	Foundation for Science and Technology, Portugal Ministry of Science
2004	Department of Defense Breast Cancer Research Program ENDO-2 Study Section EPI-Adhoc Study Section, Chair
2005	Susan G. Komen Breast Cancer Foundation Tumor Cell Biology I Study Section
2005	National Cancer Institute, NIH Cancer Epidemiology/Cancer Prevention Small Grants Study Section
2006	Susan G. Komen Breast Cancer Foundation Tumor Cell Biology V Study Section
2006	Department of Defense Breast Cancer Research Program Molecular Biology & Genetics Peer Review Panel III
2007	Susan G. Komen Breast Cancer Foundation Tumor Cell Biology I Study Section
2007	California Breast Cancer Research Program Tumor Progression Review Committee
2007	National Science Foundation (<i>ad hoc</i>)
2007	National Cancer Institute, Innovative Technologies for Molecular Analysis of Cancer (IMAT) review panel
2007	Department of Defense Breast Cancer Research Program Molecular Biology & Genetics Peer Review Panel III
2008	Susan G. Komen Breast Cancer Foundation Tumor Cell Biology I Study Section
2008	National Cancer Institute, Innovative Technologies for Molecular Analysis of Cancer (IMAT) review panel
2008	California Breast Cancer Research Program Tumor Progression Committee
2008	Israeli Science Foundation (<i>ad hoc</i>)
2008	Department of Defense Breast Cancer Research Program Molecular Biology & Genetics Peer Review Panel II
2009	Chair, DOD Breast Cancer Research Program Concept Grant Molecular Biology & Genetics Peer Review Panel I
2009	Department of Defense Breast Cancer Research Program Molecular Biology & Genetics Peer Review Panel II
2009	Foundation of UMDNJ Biomedical Research Support Program
2009	Department of Defense Breast Cancer Research Program Molecular Biology & Genetics Peer Review Panel II

17. PRINCIPAL CLINICAL AND HOSPITAL SERVICE RESPONSIBILITIES

Weekly Oncology clinic, UMDNJ- University Hospital
Service Attending two months a year in Oncology, UMDNJ-University Hospital

18. MAJOR ADMINISTRATIVE RESPONSIBILITIES

1993-present Director, Laboratory of Molecular Oncology
1996-1999 Interim Director, Division of Oncology, Department of
Medicine, UMDNJ-New Jersey Medical School
1999-2001 Interim Director, Division of Oncology/Hematology, Department of
Medicine, UMDNJ-New Jersey Medical School
1998-2001, 2006-present Chair, NJ Commission on Cancer Research Breast
Cancer Advisory Group
1998-2001 Associate Director, Clinical Research, UMDNJ-NJMS Cancer Center
1998-2003 Associate Director (clinical), P.D./PhD Program, UMDNJ-Graduate
School of Biomedical Sciences
2005-present Director, Clinical Research Office, UMDNJ-NJ Medical School/
University Hospital Cancer Center
2009-present Co-Medical Director, Center for Clinical and Translational Science,
UMDNJ-NJ Medical School

19. PRIVATE PRACTICE None

BIBLIOGRAPHY

20. ARTICLES

1. Jaynes EN, Grant PG, Giangrande G, **Wieder R**, Cooperman BS. (1978) Photoinduced affinity labeling of the Escherichia coli ribosome puromycin site. *Biochemistry* 17: 561-569.
2. **Wieder R**, Wetmur JG. (1981) One hundred-fold acceleration of DNA renaturation rates in solution. *Biopolymers* 20: 1537-1547.
3. **Wieder R**, Wetmur JG. (1982) Factors affecting the kinetics of DNA reassociation in phenol-water emulsion at high DNA concentrations. *Biopolymers* 21: 665-677.
4. **Wieder R**. (1982) Techniques for accelerating DNA renaturation and their preliminary application to gene isolation methods. Thesis. The City University of New York.
5. Cornetta K, **Wieder R**, Anderson WF. (1989) Gene transfer into primates and prospects for gene therapy in humans. *Progress in Nucleic Acids Research and Molecular Biology* 36:311-322.
6. **Wieder R**, Cornetta K, Kessler SW, Anderson WF. (1991) Increased efficiency of retroviral-mediated gene transfer and expression in primate bone marrow progenitors following 5-FU-induced hematopoietic suppression and recovery. *Blood* 77: 448-455.
7. **Wieder R**. (1991) Cryopreserved primate bone marrow cells can be used for retroviral-

mediated gene transfer. Human Gene Therapy 2: 323-326.

8. **Wieder R**, Barak V, Ben-Ishay Z. (1995) High-efficiency retroviral gene transfer into murine high-proliferative-potential cells cycle-activated by cytosine arabinoside. Human Gene Therapy 6: 865-871.

9. Menzel T, Rahman Z, Calleja E, White K, Wilson EL, **Wieder R**, Gabrilove J. (1996) Elevated intracellular level of basic fibroblast growth factor correlates with stage of chronic lymphocytic leukemia and is associated with resistance to fludarabine. Blood 87: 1056-1063.

10. Fenig E, **Wieder R**, Paglin S, Wang H, Persaud R, Haimovitz-Friedman A, Fuks Z, Yahalom J. (1997) Basic fibroblast growth factor confers growth inhibition and Mitogen-activated Protein Kinase activation in human breast cancer cells. Clinical Cancer Research 3: 135-142.

11. Wang H, Rubin M, Fenig E, DeBlasio T, Mendelsohn J, Yahalom J and **Wieder R**. (1997) Basic FGF causes growth arrest in MCF-7 human breast cancer cells while inducing both mitogenic and inhibitory G₁ events. Cancer Research 57: 1750-1757.

12. **Wieder R**, Wang H, Shirke S, Wang Q, Menzel T, Feirt N, Jakubowski AA and Gabrilove JL. (1997) Low level expression of basic FGF upregulates Bcl-2 and delays apoptosis, but high intracellular levels are required to induce transformation in NIH 3T3 cells. Growth Factors 15:41-60.

13. **Wieder R**, Fenig E, Wang H, Wang Q, Paglin S, Menzel T, Gabrilove J, Fuks Z, Yahalom J. (1998) Overexpression of basic fibroblast growth factor in MCF-7 human breast cancer cells: lack of correlation between inhibition of cell growth and MAP kinase activation. J. Cellular Physiology 177:411-425.

14. Wang Q, Maloof P, Wang H, Fenig E, Stein D, Nichols G, Denny TN, Yahalom J and **Wieder R**. (1998) Basic fibroblast growth factor (bFGF) downregulates Bcl-2 and promotes apoptosis in MCF-7 human breast cancer cells. Experimental Cell Research 238:177-187.

15. Maloof P, Wang Q, Wang H, Stein D, Denny TN, Yahalom J, Fenig E and **Wieder R**. (1999) Overexpression of retrovirally transduced basic FGF in MCF-7 human breast cancer cells downregulates Bcl-2 and sensitizes cells to chemotherapy-induced apoptosis. Breast Cancer Research and Treatment 56:153-167.

16. Fenig E, Livnat T, Sharkon-Polak S, Wasserman L, Beery E, Lilling G, Yahalom J, **Wieder R**, Nordenberg J. (1999) Basic fibroblast growth factor potentiates cisplatin-induced cytotoxicity in MCF-7 human breast cancer cells. J. Cancer Res. Clin. Onc. 125:556-562.

17. Korah R, Sysounthone V, Golowa Y, and **Wieder R**. (2000) Basic fibroblast growth factor confers a more differentiated phenotype in MDA-MB-231 human breast cancer cells. Cancer Research 60:733-740.

18. Wang Q, Yang W, Uytingco MS, Christakos S and **Wieder R**. (2000) 1,25(OH)₂ vitamin D₃ and all-*trans* retinoic acid sensitize breast cancer cells to chemotherapy-induced cell death.

Cancer Research. 60:2040-2048.

19. Korah R, Sysounthone V, Scheff E, and **Wieder R**. (2000) Intracellular FGF-2 promotes differentiation in T47-D breast cancer cells. *Biochem. Biophys. Res. Comm.* 277:255-260.
20. Wang Q, Lee D, Sysounthone V, Chandraratna RAS, Christakos S, Korah R, and **Wieder R**. (2001) 1,25-dihydroxyvitamin D₃ and retinoic acid analogues induce differentiation in breast cancer cells with function- and cell-specific additive effects. *Breast Cancer Res. Treat.* 67:157-168.
21. Fenig E, Kanfi Y, Wang Q, Beery E, Livnat T, Wasserman L, Lilling G, Yahalom J, **Wieder R** Nordenberg J. (2001) Role of transforming growth factor beta in the growth inhibition of human breast cancer cells by basic fibroblast growth factor. *Breast Cancer Res. Treat.* 70: 27-37.
22. **Wieder R**, Pavlick AC, Bryan M, Hameed M, Baredes S, Pliner L, Saunders T and Korah R. (2002) Phase I/II trial of Accutane as a potentiator of carboplatin and Taxol in squamous cell carcinomas. *American J. Clinical Oncology* 25: 447-450.
23. **Wieder R**, Novick SC, Hollis BW, Bryan M, Chanel SM, Owusu K, Camastra D, Saunders T, Pliner L, Harrison J, Bonate P, Williams T, Soignet S. (2003) Pharmacokinetics and Safety of ILX23-7553, a Non-calcemic-Vitamin D₃ Analogue, in a Phase I Study of Patients with Advanced Malignancies. *Investig. New Drugs* 21: 445-452.
24. Wang Q and **Wieder R**. (2004) All-*trans* retinoic acid potentiates Taxotere-induced cell death mediated by jun N-terminal kinase in breast cancer cells. *Oncogene* 23: 426-433.
25. Korah R, Choi L, Barrios J and **Wieder R**. (2004) Constitutive expression of FGF-2 abrogates focal adhesion signaling in MDA-MB-231 breast cancer cells. *Breast Cancer Research and Treatment* 88: 17-28 (Erratum – color photos (2005) 89: 319 – 322).
26. Korah R, Boots M, and **Wieder R**. (2004) Integrin $\alpha 5\beta 1$ promotes survival of growth-arrested breast cancer cells: an *in vitro* paradigm for breast cancer dormancy in bone marrow. *Cancer Research* 64: 4514-4522.
27. Najmi S, Korah R, Chandra R, Abdellatif M, **Wieder R**. (2005) Flavopiridol blocks integrin-mediated survival in dormant breast cancer cells. *Clinical Cancer Research* 11:2038-2046.
28. **Wieder R**. Insurgent micrometastases: sleeper cells and harboring the enemy. (2005) *J. Surgical Oncology* 89:207-210.
29. Fitzpatrick E, McBride S, Yavelow J, Najmi S, Zanzucchi P and **Wieder R**. Microfluidic techniques for single cell protein expression analysis. (2006) *Clin. Chem.* 52:1080-1088.
30. Korah R, Das K, Lindy ME, Hameed M and **Wieder R**. Co-ordinate loss of FGF-2 and laminin 5 expression during neoplastic progression of mammary duct epithelium. (2007)

Human Pathology 38:154-160.

31. Bryan M, De La Rosa N, Hill AM, Amadio WJ, **Wieder R**. (2008) Influence of prescription benefits on pain control in patients with cancer. *Pain Medicine* 9:1148–1157.
32. Dhawan P, **Wieder R**, Christakos S. (2009) CCAAT Enhancer Binding Protein Alpha is a Molecular Target of 1,25Dihydroxyvitamin D₃ in MCF-7 Breast Cancer Cells. *J. Biol. Chem.* 284:3086-3095.
33. Barrios, J and **Wieder R**. (2009) Dual FGF-2 and integrin $\alpha 5\beta 1$ signaling mediate GRAF-induced RhoA inactivation in a model of breast cancer dormancy. *Cancer Microenvironment* (in press).

21. BOOKS, MONOGRAPHS AND CHAPTERS

1. **Wieder R**, Kessler SW, Wagemaker G, Anderson WF. (1988) Differential retroviral gene transfer into primate bone marrow precursors fractionated on an albumin gradient. In: Gale RP and Champlin R, eds., *UCLA Symposia on Molecular and Cellular Biology, New Series*, vol 91: Bone Marrow Transplantation: Current Controversies, Alan R. Liss, Inc, New York, pp 379-388.
2. **Wieder, R**. Selection of Methods for Measuring Proliferation, in *Cell Growth, Differentiation and Senescence: A Practical Approach*. G. Studzinski, ed. Oxford University Press, New York, NY, 1999, pp 1-32.
3. **Wieder, R**. TUNEL assay as a measure of chemotherapy-induced apoptosis. *Methods in Molecular Medicine*, vol. 111: Chemosensitivity : Vol. 2: In Vivo Models, Imaging, and Molecular Regulators. R.D Blumenthal, ed., Humana Press, Inc., Totowa, NJ, 2005, pp 43-54.

22. ABSTRACTS

1. **Wieder R**, Wetmur JG. (1981) Optimum methods for acceleration of DNA renaturation rates. *Federation Proceedings* 40: 1849.
2. Zwiebel JA, Kantoff PW, Eglitis MA, Kohn D, Muenchau D, McLachlin JR, Karson E, **Wieder R**, Yu S-F, Blaese MR, Gilboa E, Anderson WF. (1986) Gene transfer and expression using a family of retroviral vectors. *Blood* 68: 307a.
3. Cornetta K, Moen R, Gillio A, Culver K, **Wieder R**, Blaese RM, O'Reilly R, Anderson WF. (1988) Fate of murine helper virus in non-human primates. *J Cellular Biochem, Supplement* 12B.
4. **Wieder R**, Zwiebel JA, Wagemaker G, Anderson WF. (1988) Enhanced retroviral gene transfer into primate bone marrow progenitor cells enriched by discontinuous albumin

gradients. J Cellular Biochem, Supplement 12C, K221.

5. **Wieder R**, Cornetta K, Kessler S, Anderson WF. (1988) Kinetics of 5-FU-induced bone marrow suppression and recovery: effects on the efficiency of retroviral gene transfer in non-human primates. Blood 72: 105a.

6. **Wieder R**, Cornetta K, Kessler S, Anderson WF. (1989) Improved efficiency of retroviral-mediated gene transfer and expression in primate hematopoietic progenitors following 5-FU-induced bone marrow suppression and recovery. J Cellular Biochem, Suppl. 13C, H229.

7. **Wieder R**, Shirke S, Kehagias E, Gilboa E, Rifkin DB, Wilson EL, Jakubowski AA, Gabrilove JL. (1991) Constitutive expression of retrovirally transduced basic FGF in NIH 3T3 cells causes phenotypic transformation and modulates hematopoiesis. Blood 78: 301a.

8. **Wieder R**, Shirke S, Kehagias E, Jakubowski A, Wilson EL, Gabrilove JL. (1992) In vitro stimulation of myelopoiesis by constitutive expression of basic FGF in retrovirally transduced NIH 3T3 cells. J Cellular Biochemistry, Supplement 16C, M446.

9. **Wieder R**, Shirke S, Kehagias E, Jakubowski AA, Wilson EL, Gabrilove JL. (1992) NIH 3T3 cells transduced with basic FGF stimulate myelopoiesis in vitro. J Cellular Biochemistry, Suppl. 16F, V229.

10. **Wieder R**, Shirke S, Wilson EL, Gabrilove JL. (1992) Retroviral Gene transfer of the human basic fibroblast growth factor (hbFGF) gene in human stroma. Cancer Biology and Molecular Genetics, 11:105, #241. (selected for oral presentation) (Winner of ASCO Travel Award)

11. **Wieder R**, Barak V, Ben-Ishay Z. (1992) Cycle-activation of high proliferative potential cells (HPPC) in mice administered high doses of cytosine arabinoside (Ara-C). Exp. Hem. 20:733, #113.

12. **Wieder R**, Gabrilove JL, Wilson EL, Golde DW, Raines MB. (1992) Constitutive overexpression of human basic fibroblast growth factor (bFGF) in retrovirally transduced NIH 3T3 cells causes phenotypic transformation and constitutive tyrosine phosphorylation of a 42 kD protein which co-migrates with microtubule-associated protein 2 (MAP2) kinase. Blood 80:305a.

13. Fenig E, Yahalom Y, **Wieder R**, Fuks Z, Haimovitz-Friedman A. (1994) Basic fibroblast growth factor inhibits the growth of human breast cancer cells. Proc. American Assoc. Cancer Res. 35:35. (selected for oral presentation)

14. **Wieder R**, Fenig E, Fuks Z, Yahalom J. (1994) MCF7 human breast cancer cells are negatively regulated by overexpression of basic fibroblast growth factor (bFGF). Proc.Am.Soc.Clin.Onc. 13:62, #52. (selected for oral presentation)

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EXHIBIT B

Figure 1. Nonrad GEMatrix Q series gene chip microarray analysis of MCF-7 cells incubated with and without FGF-2 for 5 days on tissue culture dishes coated with fibronectin

A.

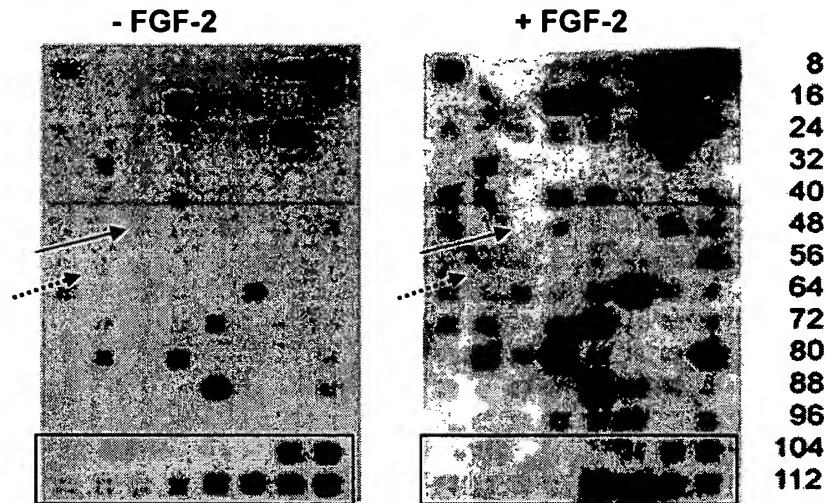


Figure 1. Nonrad GEMatrix Q series Human Extracellular Matrix and Adhesion Protein chip (Super Array, Bethesda, MD) microarray analysis of MCF-7 cells incubated for 5 days on tissue culture dishes coated with fibronectin 20 μ g with and without the presence of FGF-2 10 ng/ml. Approximately one third as many cells remained in the FGF-2-treated population as in the control cells. Arrows point to integrin α V (solid line, spot 43) and β 6 (dotted line, spot 50) mRNA's that are not expressed in the starting population and unchanged in the surviving population. Boxes are drawn around the control gene cDNAs on the two chips consisting of GAPDH, Cyclophilin A, ribosomal L23 and β actin as positive controls and PUC18 plasmid DNA and blanks as negative controls.

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Array Layout Table with Gene Symbol and Position Information

Human Adhesion & Extracellular Matrix Molecules GEArray Q series version 1

ADAMTS1 1	ADAMTS8 2	CASP8 3	CASP9 4	CAV1 5	CD44 6	CDH1 7	CEACAM5 8
CNTN1 9	COL18A1 10	COL1A1 11	COL4A2 12	CST3 13	CTNNA1 14	CTNNAL1 15	CTNNB1 16
CTNND1 17	CTNND2 18	CTSB 19	CTSD 20	CTSG 21	CTSL 22	DCC 23	ECM1 24
FGF8 25	FN1 26	HPSE 27	ICAM1 28	ITGA1 29	ITGA10 30	ITGA11 31	ITGA2 32
ITGA2B 33	ITGA3 34	ITGA4 35	ITGA5 36	ITGA6 37	ITGA7 38	ITGA8 39	ITGA9 40
ITGAL 41	ITGAM 42	ITGAV 43	ITGAX 44	ITGB1 45	ITGB2 46	ITGB3 47	ITGB4 48
ITGB5 49	ITGB6 50	ITGB7 51	ITGB8 52	LAMB1 53	LAMC1 54	MGEA5 55	MICA 56
MMP1 57	MMP10 58	MMP11 59	MMP12 60	MMP13 61	MMP14 62	MMP15 63	MMP16 64
MMP17 65	MMP2 66	MMP20 67	MMP24 68	MMP26 69	MMP3 70	MMP7 71	MMP8 72
MMP9 73	NCAM1 74	NRCAM 75	PECAM1 76	PLAT 77	PLAU 78	PLAUR 79	SELE 80
SELL 81	SELP 82	SERPINE2 83	SERPINE5 84	SERPINE1 85	SPARC 86	SPP1 87	THBS1 88
THBS2 89	THBS3 90	TIMP1 91	TIMP2 92	TIMP3 93	TMPPSS4 94	VCAM1 95	VTN 96
PUC18 97	PUC18 99	PUC18 99	Blank 100	Blank 101	Blank 102	GAPD 103	GAPD 104
PPIA 105	PPIA 106	PPIA 107	PPIA 108	RPL13A 109	RPL13A 110	ACTB 111	ACTB 112

